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July 11, 2002



BY HAND

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Citizen Petitions Requesting FDA to Regulate Candy-like Products Containing Tobacco as Adulterated Food Products (Docket Nos. 01P-0572 and 02P-0075)

Dear Sir or Madam:

On May 1, 2002, Star Scientific, Inc. ("Star") filed comments in the above-referenced dockets urging the Food and Drug Administration ("FDA") to deny the citizen petitions filed by the National Center for Tobacco-Free Kids et al. on December 18, 2001, and GlaxoSmithKline Consumer Healthcare, LP ("GSK") on February 15, 2002 (hereafter "Opposition" or "Opp."). These petitions requested FDA to take action against Star's product, Ariva™, and other candy-like products containing tobacco because, among other things, they are adulterated food products under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331-334.[1] In opposing such action, Star first asserts that Ariva is a smokeless tobacco product and, therefore, not a food product within the meaning of the FDCA. It then contends that the U.S. Supreme Court's 5-4 decision in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) ("Brown & Williamson") forbids FDA from exercising jurisdiction over purported smokeless tobacco products such as Ariva pursuant to the provisions in the FDCA governing food. As set forth below in detail, neither of Star's arguments has merit and both should be rejected by the agency.[2]

[1] The Society for Research on Nicotine and Tobacco ("SNRT") filed a citizen petition with FDA on April 23, 2002, that also urges the agency to take action against Ariva (Docket No. 02P-0205). On June 13, 2002, Star filed comments opposing this petition.

[2] Star has also challenged GSK's description of sales of Ariva over the Internet (Opp. at 14, fn. 14). On June 14, 2002, GSK filed a letter in the docket addressing this issue in detail. Although Star has been on notice of these Internet activities involving Ariva at least as of that date, and it has represented to FDA that it maintains a "monitoring program" to address such activities, certain tobacco websites continue to advertise Ariva for sale.

02P-0075 C5

I. The FDA Has Jurisdiction over Ariva and Other Candy-Like Products Containing Tobacco Since They Constitute Food Products Under the FDCA

Star erects essentially three legal arguments in support of its assertion that Ariva is not subject to FDA's jurisdiction because the product is not a "food" under the FDCA. First, it claims that GSK's interpretation of the term "food" in the FDCA to include Ariva cannot be correct since it would also encompass cigarettes, snuff, and "chewing tobacco foods" (Opp. at 6-7). In essence, Star maintains that if Ariva is a food because people like the tobacco satisfaction it provides, then the same must be true of other tobacco products. Star fails to draw the obvious line. To be sure, "the statutory definition of 'food' includes articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value." Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983) ("Nutrilab"). The test for determining whether a product constitutes a food under the FDCA, however, is more than simply whether people like it for its taste, aroma or nutritive value.[3] It also turns on the form in which the product is sold. United States v. Technical Egg Products, Inc., 171 F. Supp. 326, 328 (N.D. Ga. 1959) ("test . . . regards items as foods which are generally so regarded when sold in food form"). Indeed, it is the "everyday meaning of food" or the "article's common usage as food" that is controlling. United States v. Ener-B Nasal Gel, 888 F. Supp. 381, 387, 391-393 (E.D N.Y. 1995) (finding that a nasally administered vitamin B-12 preparation is not a food for the purposes of the FDCA). And, in contrast to cigarettes and snuff, candy-like products such as Ariva have the "everyday meaning" of, and are "generally regarded" as, food.

Perhaps in recognition of this fact, Star next argues that Ariva is not "candy-like product" because it is simply a compressed version of, and contains the same ingredients as, its new dry snuff product, Stonewall™. Star then declares that "no one has ever suggested [that Ariva] is 'candy-like'" and "Ariva does not taste like candy" (Opp. at 7-8). In the first place, even assuming arguendo that Ariva is comprised of the same ingredients as Stonewall, and Star has not provided any evidence to support that claim, it would not necessarily make a difference. That is because the term "food" in the FDCA is defined "in terms of its function as food, rather than in terms of its source, biochemical composition or ingestibility." Nutrilab at 337 (emphasis added). Moreover, while Star states that its product has not been described as "candy-like," a simple review of the literature demonstrates that the product is widely described as being similar

[3] The FDA should also not be misled by Star's mischaracterization of the Nutrilab court's broad reading of the statutory term "food" (Opp. at 9, fn.7). In pertinent part, the Court declared: "When the statute defines 'food' as 'articles used for food,' it means that the statutory definition of 'food' includes articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value. To hold as did the district court that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive since some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma, or nutritive value" (emphases added) Nutrilab at 338. Hence, Ariva could be food even if it is not used "primarily" for taste, aroma or nutritive value.

in appearance to Tic Tac® mints[4] and similar in taste to Altoid® mints.[5] Therefore, despite Star's statements to the contrary, Ariva is subject to the FDCA because it is a candy-like product.

In this context, the decision of FDA and the Department of Health and Human Services ("HHS"), on appeal, in the Masterpiece Tobacs ("Tobacs") case is instructive.[6] Tobacs was determined to be a food because it: (1) is unlike traditional smokeless tobacco products; (2) has the appearance of a piece of gum or candy; (3) utilizes a masticatory carrier base; (4) has flavors and sweeteners that make it likely that saliva is swallowed rather than expectorated; (5) is formed into a hexagon shape with a smooth, brown, edible outer coating; and (6) has an outer coating that appears in the color of chocolate. Ariva possesses virtually all of the same characteristics. It is unlike any traditional smokeless tobacco product and it certainly appears in the form of a candy. In addition, while Ariva may not contain a masticatory carrier base, it consists of other standard constituents of food (e.g., polymers, buffering agents, pH modifiers, anti-oxidants, emulsifiers) designed to prolong the disintegration and dissolution times of each candy-like unit.[7] Furthermore, Ariva has sweeteners and flavorings that encourage ingestion,

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[4] See e.g., "Cigalett Mints Target Customers Who Want Alternative to Cigarettes," Wall Street Journal, April 27, 2001, ("They're the size of Tic Tacs and taste like mints. But they pack a wallop of nicotine."); "Cigalett May Be Smoker's Answer," Richmond Times-Dispatch, April 28, 2001 ("It looks like candy, but when dissolved in the mouth it gives a dose of nicotine equal to a cigarette, the company says."); "Star Scientific Developing Tobacco," Reuters Release, April 27, 2001 ("Ariva, which is about the size of a Tic-Tac mint, would contain at least 60 percent tobacco."); "Tobacco Candy Draws Fire From Some Smoking Foes," Dallas Morning News, (Ariva is "about the size of a Tic Tac, contains compressed powdered tobacco, nicotine, and a heavy dose of mint, and isn't for sale to kids."); "Hey Buddy, Can I Bum a Cigalett?", Newsweek, ("Candy lovers, beware. They may taste like your average breath mint, but Ariva 'cigalettes -- Tic Tac-size pellets packed with powdered tobacco – deliver as much nicotine as a traditional cigarette."); "Sweets Full of Nicotine May Hook Children," UK Sunday Times, June 5, 2001, (" Tobacco companies are to launch a mint sweet containing as much nicotine as a cigarette, prompting fears that it could tempt children."); "Smokeless Tobacco Product Goes On Sale," Associated Press, Nov. 17, 2001 ("Ariva, which is about the size of a mint, is made from ground-up tobacco and flavored with eucalyptus.").

[5] Ariva has been described as "Very Similar in Taste to An Altoid Mint®" by at least two websites that offer the product for sale: www.awesomesmokes.safeshopper.com/2/94.htm?277; and http://a1discountcigarettes.safeshopper.com/9/93.htm?251.

[6] See Letter from Richard Ronk, Acting Director, Center for Food Safety and Applied Nutrition, FDA, to Stuart Pape, Patton Boggs, of September 16, 1987 (attached as Exhibit J to GSK's February 15, 2002, citizen petition); and Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, Health and Human Services, to Stuart Pape, Patton, Boggs & Blow, April 12, 1988 (attached as Exhibit G to the Petition of the National Center for Tobacco-Free Kids et al).

[7] On April 26, 2002, GSK submitted additional information to the docket in support of its petition. Among other things, that information included an analysis of the chemical constituents and physical

rather than expectoration, of saliva. Ariva is also shaped into a discrete form (i.e., an oval) with a smooth, brown, edible outer coating that appears in the color of chocolate.[8] Consequently, like Tobacs, Ariva is a food product because it is also sold in food form

Star attempts to move the focus away from this fact with one last argument – Ariva is not a food because it is not marketed as a candy product (Opp. at 8-9). Yet, that approach to defining the term "food" has consistently been rejected by the courts. Indeed, "a manufacturer cannot avoid the reach of the FDA by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption." Nutrilab at 337; see also United States v. Technical Egg Products, Inc., 171 F. Supp. 326, 328 (N.D. Ga. 1959) ("[t]he test for determining whether an item is a food under the Act cannot be one of intended use").[9] Although the intent of the vendor may be "a key element" in determining whether a product constitutes a "drug" under the FDCA, "that is not the case . . . with regard to determining whether a product is a food." United States v. Ener-B Nasal Gel, 888 F. Supp. 381, 391-392 (E.D N.Y. 1995). Rather, as the court emphasized in American Health Products Co., Inc. v. Hayes, 574 F. Supp.1498, 1505 (S.D.N.Y. 1983), it is "the ordinary way in which an article is used [and] therefore, not any marketing claim on the part of the manufacturer or distributor as to specific physiological purpose of that use, [that] should determine whether it is a food for the purpose [of the FDCA]." Consequently, it does not matter that Star characterizes Ariva as a "smokeless tobacco product" for use "when you might have a cigarette but can't." Nor does it matter that Star has sought to market Ariva as a tobacco product by complying with the rules generally governing tobacco products.

In its decision involving Tobacs, FDA rejected precisely the same argument that Star now presses. There, as here, the manufacturer of Tobacs, Pinkerton Tobacco Company ("Pinkerton"), packaged, labeled and marketed its product as a smokeless tobacco product. It also complied with the relevant rules governing smokeless tobacco products, including those provisions in the

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properties of Ariva that showed that the product contains sweeteners (e.g., glucose, fructose, mannitol), flavoring ingredients (e.g., menthol, l-carvone, jasmone, dihydrocarveol, benzaldehyde), anti-oxidants (e.g., butylated hydroxytoluene), and an emulsifier (tripropylene glycol). These ingredients are routinely treated by FDA as elements of food products. See, e.g., 21 C.F.R. § 172.515; and 21 C.F.R. § 182.20.

[8] Thus, Star cannot distinguish the Tobacs decision by emphasizing that it was a chewing gum product -- a term that is expressly included in the FDCA's definition of food. 21 U.S.C. § 321(f)(2) (Opp. at 9). Rather, FDA focused on much more than that fact. It evaluated the totality of the Tobacs product, as compared to conventional portion-packed tobacco snuff, and decided that Tobacs is a food because it "is sold in food form."

[9] Curiously, Star concedes as much, stating elsewhere in its comments that "items that are generally regarded as foods are 'foods' within the meaning of the FDCA, even if the seller claims that he does not intend to sell the items for human consumption" (Opp. at 9).

Internal Revenue Code that impose federal excise taxes on tobacco products and require businesses engaged in the manufacture of tobacco products to obtain a license from the Bureau of Alcohol, Tobacco and Firearms ("BATF"). Pinkerton then argued that FDA did not have authority to regulate Tobacs since it would be marketed and used only as a smokeless tobacco product. The FDA and HHS refused to accept this argument. Instead, after carefully reviewing the characteristics of this product and the underlying law, HHS concluded that Tobacs "is sold in food form and thus is properly regulated as food under the FDCA."[10] Along the same lines, since Ariva is also sold in food form, FDA must also conclude that the product is subject to regulation under the FDCA. This is the case even though Star claims that it is only marketing Ariva as a smokeless tobacco product.

II. The Brown and Williamson Decision Does Not Prevent FDA from Exercising Jurisdiction Over Ariva and Other Candy-like Products Containing Tobacco

In addition to arguing that Ariva is not a food product subject to the FDCA, Star contends that the Supreme Court's decision in Brown & Williamson precludes FDA from exercising jurisdiction over purported smokeless tobacco products such as Ariva. Star takes that position even though it concedes, as it must, that Brown & Williamson "did not specifically address the question whether FDA has authority to regulate tobacco products as 'foods' under the FDCA." Instead, Star maintains that the "analysis" or "reasoning" that the court used in deciding that tobacco products are not "drugs" under the FDCA "compels" the conclusion that they are not foods either (Opp. at 10). Star oversimplifies the Brown & Williamson decision and confuses the manner in which "drugs" and "foods" are regulated under the FDCA. Star also grossly overstates any potential conflict that may exist between the regulation of food products under the FDCA and smokeless tobacco products pursuant to the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"), 15 U.S.C. §§ 4401- 4408. In fact, Star completely ignores FDA's earlier legal finding that Tobacs could be simultaneously regulated under the FDCA, CSTHEA, and provisions of the Internal Revenue Code governing tobacco products. As discussed next, nothing in Brown & Williamson undermines FDA's authority to regulate Ariva in the same manner.

In Brown & Williamson, the Supreme Court addressed the question whether FDA has authority to regulate cigarettes and smokeless tobacco products as "drugs" and "medical devices" under the FDCA. To that end, the court first observed that drugs and devices can only be sold in the United States if they are "safe" and "effective" for their intended uses. Brown & Williamson at 133-134. On the basis of those requirements, the court indicated that FDA must "prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'" Id. at 134. (citing United States v. Rutherford,

[10] See Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, Health and Human Services, to Stuart Pape, Patton, Boggs & Blow, April 12, 1988, at pg. 2 (attached as Exhibit A)

442 U.S. 544, 556 (1979)). The court then evaluated the wealth of information available about traditional tobacco products, and concluded that they could not be marketed in the United States under this standard because of the "extraordinary health risks" they presented. Id. at 135-137.[11] However, that result, the court declared, would be inconsistent with legislation enacted by Congress allowing for marketing of such tobacco products in this country. Id. at 137-139. As a result, the court held that FDA may not regulate cigarettes and smokeless tobacco products pursuant to the strict safety and efficacy standards governing drugs and devices in the FDCA.

In its comments opposing GSK's petition, Star invokes broad language from Brown & Williamson in the hope that it can fold Ariva within the court's narrow holding. In doing so, Star ignores at least five important distinctions that bring its product within the jurisdiction of FDA. First, GSK is asking FDA to regulate Ariva under an entirely different regulatory scheme than that at issue in Brown & Williamson. The FDCA's provisions governing foods afford FDA much more flexibility than the drug and device provisions, and they certainly do not mandate a showing of therapeutic benefit before a product can be marketed. To be sure, the statute does provide that a "food shall be deemed to be adulterated if it is, or it bears or contains any food additive which is unsafe within the meaning of Section 409." 21 U.S.C. § 342(a)(2)(A). But, in contrast to the statutory provisions at issue in Brown & Williamson, the latter provision grants FDA substantial discretion to consider various factors in determining the safety of a food additive. 21 U.S.C. § 348(c)(5). It also gives FDA broad authority to prescribe the particular conditions under which an additive may be safely used in food, including the maximum quantity of the additive that may be used and any labeling requirements deemed necessary to assure the safety of an additive. 21 U.S.C. § 348(c)(1).

Second, Star does not recognize that, in contrast to the statutory provisions at issue in Brown & Williamson, no fatal or irreconcilable conflict exists between those sections in the FDCA governing food and the requirements in the CSTHEA pertaining to smokeless tobacco products. This was precisely the conclusion of both FDA and HHS in the Tobacs cases in response to the very same arguments that Star now makes. Specifically, Pinkerton argued that the CSTHEA established an "exclusive regulatory scheme" for smokeless tobacco products. Writing in support of FDA, HHS found that FDA's authority to regulate food products containing tobacco was only limited by Section 7(a) of the CSTHEA, which forbids FDA from requiring a warning statement relating to the use of smokeless tobacco products and health.[12]

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[11] The court was also obviously moved by numerous statements from FDA over the years in which the agency conceded that it did not have authority to regulate traditional tobacco products. Brown & Williamson at 144-146. Of course, FDA has never taken that position for food products containing tobacco such as Tobacs.

[12] This provision reads in full: "No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product." 15 U.S.C. § 4406(a). In its petition, GSK

Nothing in that provision or any other section of the CSTHEA prevents FDA from regulating the composition of a smokeless tobacco product under the FDCA. Moreover, to the extent that one provision in the FDCA concerning disclosure of ingredients created a potential conflict with the disclosure requirements of the CSTHEA, HHS found that these provisions could be "easily harmonized."[13] As a result, and with the concurrence of both the FTC and BATF, HHS concluded that food products containing tobacco can be regulated under both the FDCA and CSTHEA.[14]

Third, Star fails to mention that Ariva has been designed to be "safer" than the traditional tobacco products at issue in Brown & Williamson. Rather, in its comments opposing GSK's petition, Star treats Ariva like any other tobacco product for the purposes of Brown & Williamson – that is, "unsafe" and "dangerous." Star must characterize Ariva in this manner to create the statutory conflict it needs to exempt the product from FDA's jurisdiction. Yet, elsewhere, Star has made statements about Ariva that demonstrate that a such conflict need not exist. For example, Star has stated that, "[u]nlike smoked tobacco, Ariva does not contain hundreds of toxic chemical constituents that are caused by the burning of tobacco."[15] At the

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described the narrow manner in which this provision has been construed by the courts. See e.g., Philip Morris, Inc. v. Harshbarger, 122 F.3d 58, 77-78 (1st Cir. 1997).

[13] This was the only possible conflict that HHS identified. In pertinent part, the CSTHEA provides that information about the ingredients in a smokeless tobacco product that is submitted by manufacturers to HHS is to be treated as "trade secret or confidential information" under the Freedom of Information Act ("FOIA"). 15 U.S.C. § 4403(b)(2)(A). On the other hand, under the FDCA, ingredient lists are to be included on a product's label. 21 U.S.C. § 343(I)(2). The latter provision, however, authorizes FDA to establish exemptions to this requirement to the extent that compliance is "impracticable" or "results in deception or unfair competition." HHS indicated that it was prepared to create such an exception for Tobacs on the basis of the latter exception since the CSTHEA's ingredient disclosure provision is intended to ensure that competitors do not gain an unfair competitive advantage. Accordingly, GSK is hardly asking FDA "to stretch the food provisions of the FDCA to cover tobacco products" nor is GSK "underestimat[ing] the scope of the conflict between the FDCA and the nation's tobacco laws," as Star suggests (Opp. at 17-18).

[14] Star places great emphasis on the BATF's actions with respect to Ariva, alluding to the agency's purported classification of Ariva as a smokeless tobacco product no fewer than three times (Opp. at 1, 4, 15). Star's reliance on the BATF is disingenuous since the company openly invited BATF to exercise jurisdiction over Ariva and the BATF almost certainly did not consider the issue when it granted Star a license to manufacture Ariva. In any event, as FDA's decision in the Tobacs case makes clear, the BATF's decisions are not controlling here since Ariva can simultaneously be subject to the jurisdiction of the BATF as a smokeless tobacco product and FDA as a food product.

[15] See "What is Ariva™?", Attachment #3, Star Opposition. Elsewhere, Star declares: "There is a substantial difference between the numbers and levels of toxic constituents in smoked, and in smokeless tobacco products. There are 4,000 chemical constituents in tobacco smoke, 43 of which are known or

same time, Star has repeatedly emphasized that Ariva utilizes a specially formulated tobacco (StarCured™) that contains much lower levels of tobacco specific nitrosamines ("TSNAs") than tobacco used in other products.[16] In this connection, Star has emphasized that "[r]espected scientists worldwide believe that TSNAs are among the most potent and abundant carcinogens in tobacco leaf and smoke."[17] Hence, just based on Star's own description of its product, Ariva is fundamentally different from traditional tobacco products on the key point -- safety -- that led the Supreme Court to exempt such products from FDA regulation.

Fourth, Star overstates the consequences of the regulatory action requested in GSK's petition in order to bring it within the ambit of the Brown & Williamson decision. GSK is only asking FDA to require Star to file a food additive petition that addresses the safety of the tobacco added to Ariva. This is a perfectly reasonable request in light of Star's own claims about the "safer" use of Ariva and the company's stated commitment to the regulation of all tobacco products by FDA.[18] Star nonetheless asserts that if it is required to submit such a petition, that action would be inconsistent with Brown & Williamson because it would not allow Star to

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suspected carcinogens. Smokeless tobacco, however, is not burned and therefore the user is exposed to many fewer carcinogens. Public health authorities have determined that there are only a handful of toxins that are of concern in smokeless tobacco, and of this handful only the nicotine and TSNA's appear to be at levels that are likely linked to health problems." See "Questions and Answers," Attachment #2, Star Opposition.

[16] Star claims that '[t]he tobacco in Ariva(TM) is 100% Virginia, StarCured(TM) tobacco, which the company believes contains the lowest levels of tobacco-specific nitrosamines (TSNAs) in the world." See Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigaletts; Test Markets Initiated in Dallas, Texas and Richmond, VA, November 14, 2001, Attachment #1, Star Opposition. For similar statements, see also Star Scientific and B&W Enter Into Contracts for Purchases of StarCured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products, April 27, 2001; and Star Scientific, Inc. Announces New Patent for Products Containing Very Low Levels of Cancer-Causing Tobacco Specific Nitrosamines, October 24, 2000.

[17] See Letter from Paul Perito, Chairman, President and Chief Operating Officer, Star Scientific, Inc., to Nick Tomlinson, Head, Novel Foods Division, Food Standards Agency, of May 17, 2001 (attached as Exhibit B to GSK's petition).

[18] Star declares that it "supports efforts to give FDA jurisdiction to implement fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of *all* tobacco products" (Opp. at 19). But, it then goes on to state that Ariva is not subject to FDA regulation because it must be treated like all other smokeless tobacco products (Opp. at 20). Star cannot have it both ways. While going to great lengths to distinguish Ariva from other smokeless tobacco products on the market, Star lumps Ariva with these products for the purposes of FDA regulation. Since Star is marketing a food product containing tobacco, it must subject that product to regulation by the FDA under the applicable provisions of the FDCA.

market Ariva immediately. Star is incorrect. While it is true that Star would have to await FDA's decision on a food additive petition before marketing Ariva, that delay does not mean that Ariva may not ultimately reach the market. Star itself concedes that Ariva could be marketed if FDA determines, on the basis of a food additive petition, that tobacco can be safely used as a food additive in Ariva (Opp. at 18). This contrasts sharply with the Supreme Court's finding that the drug and device provisions of the FDCA simply do not allow cigarettes and smokeless tobacco products to be marketed in the United States. Here, there is a statutory mechanism that could allow for marketing of Ariva -- Star must first avail itself of these procedures before complaining about the possible results.[19]

Finally, Star fails to acknowledge that Ariva is not subject to the Brown & Williamson holding because it is not a "traditional tobacco product." In its petition, GSK raised this argument in the alternative because it is not necessary for FDA to resolve this issue in order to pursue the regulatory action requested in the petition. Despite that fact, Star spends considerable time challenging GSK's interpretation. For example, Star maintains that Brown & Williamson did not hold that FDA lacks jurisdiction to regulate only traditional tobacco products (Opp. at 16). In support of that assertion, Star points out that the court and relevant statutes nowhere refer to "traditional" tobacco products.[20] As Star itself explained, however, the Brown & Williamson decision is premised on the notion that Congress intended to allow marketing of those products that are governed by the "tobacco-specific statutes" (Opp. at 11). And, what Star fails to recognize is that the products that are subject to regulation under these statutes are traditional products such as cigarettes, chewing tobacco and snuff. Hence, while the phrase "traditional tobacco products" may not appear in the court's decision (and GSK never maintained that it did), the court was obviously focused on such products when it rendered its decision.

As GSK demonstrated in its petition, Ariva can hardly be considered a "traditional tobacco product" since it does not fit into the statutory definition of "smokeless tobacco product" under the CSTHEA. Indeed, Ariva is much more than simply "finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1). Star itself describes Ariva as "innovative" and as a "flagship" product.[21] Nevertheless, for the purposes of

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[19] Star also cannot complain about the delay that may result from this process. Star could have commenced this process long ago by acknowledging that its product is a food subject to the FDCA and filing a food additive petition evaluating the safety of the StarCured tobacco in Ariva.

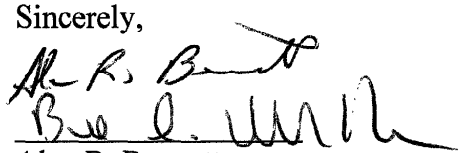
[20] In this context, Star also plays down the Supreme Court's use of the phrase "tobacco products as customarily marketed" (Opp. at 16). As GSK indicated in its petition, this limiting language makes clear that the court was focused on traditional tobacco products when it considered the scope of FDA's authority over such products as drugs and devices.

[21] See "Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigaletts; Test Markets Initiated in Dallas, Texas and Richmond, VA," November 14, 2001, Attachment #1, Star Opposition;

avoiding FDA regulation under Brown & Williamson, Star once again lumps Ariva with other smokeless tobacco products on the market, including powdered snuff, whole or ground loose leaf tobacco, individual pouches, and hardened blocks or ropes of tobacco. Unlike Ariva, those products appear in the form of raw tobacco itself -- a key element in the CSTHEA's definition of smokeless tobacco -- rather than tobacco that has been hardened or "compressed" into a candy-like product closely resembling a mint. Moreover, in contrast to Ariva, these products are clearly meant to be placed only in the oral cavity -- the other defining characteristic of a smokeless tobacco product. On the other hand, Ariva is designed to be ingested through the saliva created by working the product in one's mouth. Accordingly, while FDA need not reach this determination in order to take the action requested in GSK's petition, Ariva also does not meet either prong of the CSTHEA's definition of smokeless tobacco product. As a result, for that reason and based on the foregoing discussion, Brown & Williamson does not forbid FDA from exercising jurisdiction over Ariva.

Thank you for your consideration of these comments.

Sincerely,



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cc: Lester Crawford, Deputy Commissioner, FDA
Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, FDA

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"Star Scientific And B&W Enter Into Contracts for Purchases Of StarCured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products,"(attached as Exhibit E, GSK Petition).